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PATENT

PATENT &amp; TRADEMARK OFFICE

## THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Legerton et al.	)	Group Art Unit 2873
Appl. No.	:	10/657,061	)	
Filed	:	September 5, 2003	)	
For	:	HYBRID CONTACT LENS SYSTEM AND METHOD	)	
Examiner	:	Jessica T. Stultz	)	

**DECLARATION OF JEROME LEGERTON PURSUANT TO 37 C.F.R. § 1.132**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, Jerome Legerton, declare and state as follows:

1. I am a United States citizen and I reside at 874 Harbor View Place, San Diego, CA 92106.
2. I am a named inventor in the above-identified application.
3. I am currently Executive Vice President and Chief Technology Officer of Synergeyes, Inc. Prior to this, I was the managing partner of an eight doctor multi-specialty optometric practice in San Diego, California. From 1985 to 2004, I also served as a consultant for ophthalmic corporations including Dicon, Barnes Hind-Hydrocurvc, VISX, Alcon, Akorn, and Anamed. From 1994 to 1996, I served as Director of Clinical Research at Pilkington Barnes Hind. From 1997 to 2002, I served as Vice President of Advanced Technology and Market Development for Paragon Vision Sciences.
4. I hold a Doctor of Optometry from Los Angeles College of Optometry, a Master of Science degree in Counseling from Trinity School of Graduate Studies, and a Master of Business Administration from Pepperdine University.

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5. I am a Life Member and Presidents Circle Member of the American Optometric Foundation and a Life Member of the Southern California College of Optometry Alumni Association. I have been a Member of the American Optometric Association since 1966 and a Fellow of the American Academy of Optometry since 1973. I was named "Young Optometrist of the Year" by the California Optometric Association in 1973. I served as President of the San Diego Optometric Society and named its "Optometrist of the Year" in 1987. I am an Associate Member of the Contact Lens Association of Ophthalmologists.

6. I am a named inventor in five issued patents in the field of contact lenses and refractive surgery. I have authored numerous publications and technical reports and made numerous technical presentations, many of which involve contact lenses and/or the cornea.

7. I have worked in the contact lens industry for the past 37 years, including the research and development of contact lens designs, including hybrid contact lenses, materials, and solutions. I also have knowledge of hybrid contact lens designs that have been commercialized. The commercially available SoftPerm hybrid contact lens had a low DK center (DK of about 14) and low DK peripheral skirt (DK of about 5). I understand that one major problem with the SoftPerm lens is that it delaminated at the junction between the hard center and the soft skirt. It is my understanding that the SoftPerm lens continues to have tearing problems. The SoftPerm lens is the only commercially available hybrid contact lens.

8. I have reviewed the pending claims in the above-identified application. I have also reviewed GB Patent No. 1,417,650 ("Sohnges") and U.S. Patent No. 5,986,001 ("Ingenito"), the two references I understand the Examiner has used to reject the pending claims as being obvious. I disagree that the pending claims are obvious in view of Sohnges and Ingenito.

9. In my opinion, the combination of Sohnges and Ingenito would not render the pending claims obvious to one of ordinary skill in the art for at least the following reasons:

10. Sohnges does not disclose a hybrid contact having a hard central portion with a DK of at least  $30 \times 10^{-11}$ . In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens. Further, Sohnges discloses microlenses, which are smaller than the diameter of a human cornea. If the lens of Sohnges was larger so as to serve the purpose of a hybrid contact lens, the lens would be too large to permit tear pumping or movement under

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the lens and would starve the cornea of oxygen. Moreover, Sohnges teaches away from using a hydrophilic skirt, and the materials identified in Sohnges are not hydrophilic. Indeed, there is no disclosure or suggestion in Sohnges to 1) provide a high DK central portion, 2) provide a hydrophilic skirt, or 3) bonding a high DK central portion to a hydrophilic skirt in any manner.

11. With respect to Ingenito, the lens disclosed uses an interpenetrating network of preformed uncrosslinked polymers. This combination results in a flexible material which is incompatible with the function of the rigid center in a hybrid contact lens. In addition, the uncrosslinked polymers disclosed in Ingenito could not be used as the soft peripheral skirt in a hybrid contact lens. The Ingenito lens is formed through softening and compressing the polymer mixture. There is no bonding occurring. Further, there is no suggestion to bond the material of Ingenito with any other material, let alone that disclosed in Sohnges. Therefore, one of skill in the art looking at these two references would not be able to combine the non-reactive uncrosslinked polymers of Ingenito with the material in Sohnges.

12. In order to provide a comfortable lens, it is important that the lens be wide enough to cover at least the cornea, which prevents the lens from excessive movement and eyelid interaction. With respect to hard contact lenses, although they provide superior vision, movement of the lens occurred often, causing discomfort with every blink. Further, foreign objects are free to migrate under the hard lens with tear exchange, causing pain and corneal trauma. With soft lenses, it is possible to manufacture a wider lens, which experiences less movement in the eye and less movement caused by eyelid interaction, resulting in less discomfort, and foreign bodies are prevented from migrating under the lens. However, soft lenses do not provide the visual quality of the rigid optics of a hard lens.

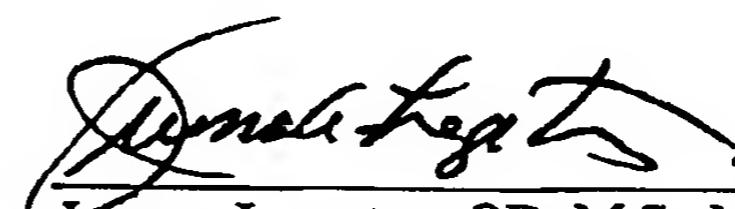
13. Therefore, there has been a long-felt need in the industry for a hybrid contact lens having a hard central portion with a high DK providing high quality vision and high oxygen permeability and a soft peripheral skirt providing greater comfort, as described above. I am aware since at least as early as 1988 of attempts that have been made to manufacture an improved hybrid contact lens. To the best of my knowledge, none of these efforts ever succeeded resulting in a commercial product.

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14. In view of the long-standing efforts by others, and my knowledge of the contact lens industry over the past thirty-seven years, I do not believe the claimed invention recited in the pending claims of the above-identified application are obvious in view of Sohnges and Ingenito.

15. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

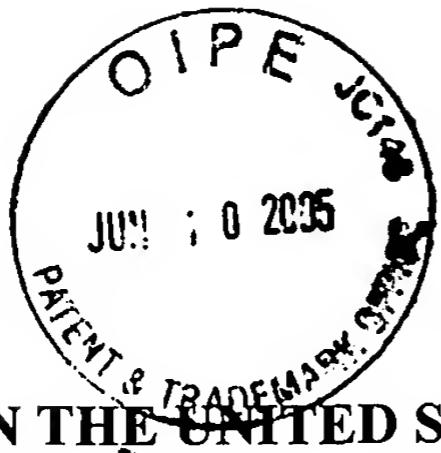
Dated: JUNE 3, 2005



Jerome Legerton, OD, M.S., M.B.A., F.A.A.O.

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Legerton et al.	) Group Art Unit 2873
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Examiner	:	Jessica T. Stultz	)

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## DECLARATION OF JOSEPH T. BARR PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, Joseph T. Barr, declare and state as follows:

1. I am a United States citizen and I reside at 2212 Gnarled Pine Drive, Dublin, OH 43016.
2. I am currently a Professor at Ohio State University. I've been a professor for fifteen years and affiliated with the University for at least twenty-two years. I am also Associate Dean for Clinical Services and Professional Programs, and Director of the NEI-sponsored Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Photography Reading Center. I also served as Chief of the Contact Lens Clinical Service at Ohio State from 1983 to 1988. Prior to this, I worked at Dow Corning for three years, where, among other projects, I worked on the development of the silicon elastomer lens. While at Dow Corning, I was the director of clinical and material research.
3. I hold a Doctor of Optometry, a Master's Degree in Physiological Optics, and a Residency Certificate from Ohio State University.

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Filed : **September 5, 2003**

4. I am the immediate past Chair of the American Academy of Optometry Cornea and Contact Lens Section. Since 1977, I have been a member of the American Optometric Association (AOA) and a member of the International Society of Contact Lens Research. Since 1990, I have been a member of the International Association of Contact Lens Educators. Since 1983, I have been a member of the Association of Optometric Contact Lens Educators.

5. Since 1988 I have been Editor of the professional journal *Contact Lens Spectrum*, which publishes articles on advances in contact lens design, manufacturing methods, materials and fitting. I have knowledge of research, successful and failed contact lens designs, and the commercialization of contact lens designs over the past twenty years.

6. I have authored numerous publications and technical reports and made numerous technical presentations, many of which involve contact lenses and/or the cornea.

7. I have worked in the contact lens industry for the past twenty-eight years, including the research and development of contact lens designs, including hybrid contact lenses, materials, and solutions. Further, I've been involved in research related to the SoftPerm hybrid contact lens, and worked with the corneal reaction of hybrid contact lenses. I also have knowledge of hybrid contact lens designs that have been commercialized. The commercially available SoftPerm hybrid contact lens had a low DK center (DK of about 12) and low DK peripheral skirt (DK of about 5). I understand that one major problem with the SoftPerm lens is that it delaminated at the junction between the hard center and the soft skirt. It is my understanding that the SoftPerm lens continues to have tearing problems. The SoftPerm lens is the only commercially available hybrid contact lens.

8. I have reviewed the pending claims in the above-identified application. I have also reviewed GB Patent No. 1,417,650 ("Sohnges") and U.S. Patent No. 5,986,001 ("Ingenito"), the two references I understand the Examiner has used to reject the pending claims as being obvious. I disagree that the pending claims are obvious in view of Sohnges and Ingenito.

9. In my opinion, the combination of Sohnges and Ingenito would not render the pending claims obvious to one of ordinary skill in the art for at least the following reasons:

10. Sohnges does not disclose a hybrid contact having a hard central portion with a DK of at least  $30 \times 10^{-11}$ . In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear

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pumping or movement under the lens. Further, Sohnges discloses microlenses, which are smaller than a human cornea. If the lens of Sohnges was larger so as to serve the purpose of a hybrid contact lens, the lens would be too large to permit tear pumping or movement under the lens and would starve the cornea of oxygen. Moreover, Sohnges teaches away from using a hydrophilic skirt, and the materials identified in Sohnges are not hydrophilic. Indeed, there is no disclosure or suggestion in Sohnges to 1) provide a high DK central portion, 2) provide a hydrophilic skirt, or 3) bonding a high DK central portion to a hydrophilic skirt in any manner.

11. With respect to Ingenito, the lens disclosed uses an interpenetrating network of preformed uncrosslinked polymers. This combination results in a flexible material which is incompatible with the function of the rigid center in a hybrid contact lens. In addition, the uncrosslinked polymers disclosed in Ingenito could not be used as the soft peripheral skirt in a hybrid contact lens. The Ingenito lens is formed through softening and compressing the polymer mixture. There is no bonding occurring. Further, there is no suggestion to bond the material of Ingenito with any other material, let alone that disclosed in Sohnges. Therefore, one of skill in the art looking at these two references would not be able to combine the non-reactive uncrosslinked polymers of Ingenito with the material in Sohnges.

12. In order to provide a comfortable lens, it is important that the lens be wide enough to cover at least the cornea, which prevents the lens from excessive movement and eyelid interaction. With respect to hard contact lenses, although they provide superior vision, movement of the lens occurred often, causing discomfort with every blink. Further, foreign objects are free to migrate under the hard lens with tear exchange, causing pain and corneal trauma. With soft lenses, it is possible to manufacture a wider lens, which experiences less movement in the eye and less movement caused by eyelid interaction, resulting in less discomfort, and foreign bodies are prevented from migrating under the lens. However, soft lenses do not provide the visual quality of the rigid optics of a hard lens.

13. Therefore, there has been a long-felt need in the industry for a hybrid contact lens having a hard central portion with a high DK providing high quality vision and high oxygen permeability and a soft peripheral skirt providing greater comfort, as described above. I am aware since at least as early as 1988 of attempts that have been made to manufacture an

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improved hybrid contact lens. To the best of my knowledge, none of these efforts ever succeeded resulting in a commercial product.

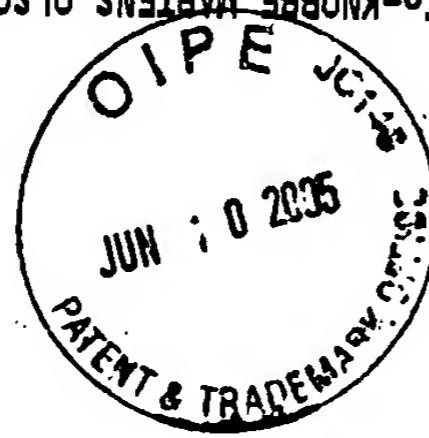
14. In view of the long-standing efforts by others, and my knowledge of the contact lens industry over the past twenty-eight years, I do not believe the claimed invention recited in the pending claims of the above-identified application are obvious in view of Sohnges and Ingenito.

15. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Dated: 6/7/05

Joseph T. Barr, OD, M.S.

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Examiner	:	Jessica T. Stultz	)

## DECLARATION OF DR. JAMES A. BOUCHER PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, James A. Boucher, declare and state as follows:

1. I am a United States citizen, and I reside at 1050 Granito Drive, Laramie, Wyoming 82072.
2. I am currently a Doctor of Optometry at Snowy Range Vision Center, 405 South 30<sup>th</sup> Street, Laramie, Wyoming, 82070, where I have worked continuously since August, 1966, and where my duties include general optometric practice with an emphasis in cornea and contact lenses. Prior to holding this position, I was an optometry officer in the United States Air Force for 3 years from 1961 to 1964 where my duties included optometric practice for military personnel and their dependants. From 1964 to 1966 I was a graduate student, teaching assistant and researcher at the Indiana University, School of Optometry in Bloomington, Indiana where I gained additional experience with contact lenses and research methodology. I have worked in the contact lens industry for the past 44 years.
3. I have a Doctorate in Optometry and a Bachelor of Science from Southern College of Optometry in Memphis, Tennessee, a Masters of Science degree in Physiological Optics from

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Indiana University, School of Optometry. I also hold two Honorary Doctorates of Ocular Science from the New England College of Optometry and the Southern College of Optometry.

4. Since 1966 I have been a member of the Wyoming Optometric Association and served as its President from 1976 to 1978. I have been a member of the American Optometric Association since 1961 and served as Chairman of the American Optometric Association's Contact Lens Section from 1986 to 1987. I served as a member and consultant of the United States Food & Drug Administration's Ophthalmic Devices Section from 1977 to 1995. For my FDA service I received the Harvey W. Wiley Medal / Food and Drug Administration Commissioner's Special Citation in 1995 for my outstanding service to the FDA in the contact lens field.

5. I served on the American National Standards Institute (ANSI) contact lens sub-committee where I assisted in developing the ANSI standards for contact lenses.

6. I have been a Fellow of the American Academy of Optometry since 1965 and a Diplomate of the Cornea and Contact Lens Section since 1993.

7. I served in the Wyoming House of Representatives from 1975 to 1977.

8. I have authored numerous publications and technical reports and made numerous technical presentations, many of which involve the cornea and contact lenses. A list of my publications can be found in my CV which is attached hereto.

9. I have worked in the contact lens industry for the past 44 years, including the research and development of gas permeable and non-gas permeable rigid, hybrid and soft lenses. Further, I've been involved in research related to these types of lenses. I served as a Principal Investigator for FDA Class II pre market notification clinical trials of the SynergEyes™ high Dk hybrid lens for Quarter Lambda Technologies, Inc., the owner of the pending patent application. I do not hold stock or any ownership interest in Quarter Lambda Technologies, Inc. I have worked with the design and methods of fitting hybrid contact lenses and have knowledge of hybrid contact lens designs that have been commercialized. To the best of my knowledge all commercially available hybrid contact lenses have a low DK center and low DK skirt. I understand that a major problem with these commercial lenses is that they can separate at the junction between the hard center and the soft skirt. Other major problems of these lenses include low oxygen transmission to the eye, undesirable lens flexure and the failure of the design to provide tear exchange.

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10. I have reviewed the pending claims in the above-identified application. I have also reviewed GB Patent No. 1,417,650 ("Sohnges") and U.S. Patent No. 5,986,001 ("Ingenito"), the two references I understand the Examiner has used to reject the pending claims as being obvious. I disagree that the pending claims are obvious in view of Sohnges and Ingenito.

11. In my opinion, the combination of Sohnges and Ingenito would not render the pending claims obvious to one of ordinary skill in the art for at least the following reasons:

12. Sohnges does not disclose a hybrid contact having a hard central portion with a DK of at least  $30 \times 10^{-11}$ . In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens. Further, Sohnges discloses microlenses, which are smaller than a human cornea. If the lens of Sohnges was larger so as to serve the purpose of a hybrid contact lens, the lens would be too large to permit tear pumping or movement under the lens and would starve the cornea of oxygen. Moreover, Sohnges teaches away from using a hydrophilic skirt, and the materials identified in Sohnges are not hydrophilic. Indeed, there is no disclosure or suggestion in Sohnges to 1) provide a high DK central portion, 2) provide a hydrophilic skirt, or 3) bonding a high DK central portion to a hydrophilic skirt in any manner.

13. With respect to Ingenito, the lens disclosed uses an interpenetrating network of preformed uncrosslinked polymers. The use of uncrosslinked polymers results in lenses that demonstrate undesirable flexure from forces exerted by the eyelids or in the case of hybrid lenses from the surrounding soft skirt. Flexure can render the lens inadequate for the correction of astigmatism or can induce an undesirable astigmatic error to the lens eye optical system. The interpenetrating network of preformed uncrosslinked polymers results in a flexible material which is incompatible with the function of the rigid center in a hybrid contact lens. In addition, the uncrosslinked polymers disclosed in Ingenito could not be used as the soft peripheral skirt in a hybrid contact lens. The Ingenito lens is formed through softening and compressing the polymer mixture. There is no bonding occurring. Further, there is no suggestion to bond the material of Ingenito with any other material, let alone that disclosed in Sohnges. Therefore, one of skill in the art looking at these two references would not be able to combine the non-reactive uncrosslinked polymers of Ingenito with the material in Sohnges.

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14. In order to provide a comfortable lens, it is important that the lens be wide enough to cover at least the cornea, which prevents the lens from excessive movement and eyelid interaction. With respect to hard contact lenses, although they provide superior vision, movement of the lenses occurred often, causing discomfort with every blink. Further, foreign objects are free to migrate under the hard lenses with tear exchange, causing pain and corneal trauma. With soft lenses, it is possible to manufacture larger overall diameter lenses which conform more closely to the asymmetric surface of the eye. These lenses demonstrate less movement in the eye and less movement caused by eyelid interaction, resulting in less discomfort, and foreign bodies are prevented from migrating under the lens. However, soft lenses do not provide the visual quality of the rigid optics of hard lenses.

15. Therefore, there has been a long-felt need in the industry for a hybrid contact lens having a hard central portion with a high DK providing high quality vision and high oxygen permeability and a soft peripheral skirt providing greater comfort, as described above. I am aware since at least as early as the late 1980's of attempts that have been made to manufacture an improved hybrid contact lens. To the best of my knowledge, none of these efforts ever succeeded resulting in a commercial product.

16. In view of the long-standing efforts by others, and my knowledge of the contact lens industry over the past 44 years, I do not believe the claimed invention recited in the pending claims of the above-identified application are obvious in view of Sohnges and Ingcnito.

17. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Dated: 06/10/05

  
James A. Boucher, OD, MS, FAAO

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**CURRICULUM VITAE**  
**MAY 2005**

**JAMES A. BOUCHER**

Business Address: 405 South 30<sup>th</sup> Street  
P.O. Box 927, Laramie, WY 82073-0927  
Office Phone: (307) 742-2020  
Fax Number: (307) 742-8917  
Home Address: 1050 Granito, Laramie, WY 82072  
Home Phone: (307) 742-3249  
email: boucher@snowyrangevision.com

**EDUCATION**

Ohio Wesleyan University	Math, Physics
Southern College of Optometry	B.S.,O.D. (1961)
Indiana University	M.S. Physiological Optics (1966)

**HONORARY DEGREES**

Doctor of Ocular Science (D.O.S.) New England College of Optometry (1986)  
Doctor of Ocular Science (D.O.S.) Southern College of Optometry (2004)

**CONTINUING EDUCATION**

Optometry Recognition Award (minimum 50 hours CE/year)(1978-Present)  
OMNI Eye Services/Colorado; Clinical Preceptorship-One Day Post Op, 6 hours  
Pacific University; Advanced Ocular Therapeutics Course 1994, 44 hours  
Pacific University; Systemic Therapy Course 1994,12 hours  
Diplomate; Cornea and Contact Lenses, American Academy of Optometry, 1993  
National Eye Research Foundation - Certification in Contact Lenses (1983)  
OMNI Eye Services/Colorado; Clinical Preceptorship, November, 1988, 44 hours  
Pennsylvania College of Optometry; Ocular Therapy for the Optometric  
Practitioner, Course Number 750B, September, 1985 - April, 1986,100 hours  
University of Wyoming/Southern California College of Optometry;  
Diagnostic Pharmaceutical Course 1975-1976, 55 hours.

**PROFESSIONAL JOB EXPERIENCE**

Optometrist - Private Practice, Laramie, Wyoming (1966-Present)  
Adjunct Professor – Illinois College of Optometry (2000-2004)  
Adjunct Professor - College of Optometry, University of Houston (1996-1997)  
Adjunct Clinical Faculty - Pacific University, College of Optometry (1979-1980) (1995 - 2003)  
Adjunct Professor - College of Health Sciences, University of Wyoming (1985-Present)  
Adjunct Associate Professor - College of Health Sciences, University of Wyoming (1982-1985)  
Lecturer in Psychology - Faculty Position at University of Wyoming (1971-1981)  
Teaching Assistant - School of Optometry, Indiana University, Bloomington, Indiana (1964-1966)  
United States Air Force Optometry Officer (1961-1964)

James A. Boucher

HOSPITAL APPOINTMENTS

Ivinson Memorial Hospital; Allied Health Professional Staff - Optometrist (1998-Present)

HONORS - PROFESSIONAL

Lifetime Achievement Award, Southern College of Optometry (1999)  
The Harvey W. Wiley Medal/ Food and Drug Administration Commissioner's  
Special Citation (1995)

National Academy of Practice in Optometry - Founder (1983-Present)  
Beta Sigma Kappa - Optometric Honorary (1981-Present)  
American Optometric Association - National Optometrist of the Year (1978)  
Alpha Epsilon Delta - Pre-Medical Honor Society - Honorary Member (1977-Present)  
Fellow, American Academy of Optometry (1965-Present)  
National Aeronautic and Space Administration Fellowship - Indiana  
University (1964-1965)

HONORS - CIVIC

Distinguished Service Award, Laramie, Wyoming, Laramie's  
Outstanding Young Man (1972)  
Distinguished Service Award, State of Wyoming, Wyoming's Outstanding  
Young Man (1972)  
Outstanding Young Men of America (1972)

PROFESSIONAL LICENSES IN OPTOMETRY

Colorado, July 1967  
    Certified Diagnostic Drugs, 1980  
    Certified Therapeutic Drugs, 1988  
National Optometry Boards, July 1965  
Washington, July 1964  
Wyoming, October, 1963  
    Certified, Diagnostic Drugs, 1978  
    Certified, Therapeutic Drugs, 1987 (Topical) 1995 (Oral)  
Michigan, July 1961

PROFESSIONAL MEMBERSHIPS

Fellow, American Academy of Optometry  
American Optometric Association  
American Optometric Foundation  
American Public Health Association  
Wyoming Optometric Association  
Colorado Optometric Association  
Contact Lens Association of Ophthalmologists  
America Public Health Association  
International Society of Refractive Surgery

James A. Boucher

## PROFESSIONAL ACTIVITIES

### General

Member; Board of Trustees, Southern College of Optometry (August 1996- 2004)  
Chair (September 2001 – 2002)  
Consultant; U.S. Department of Health and Human Services; Food and Drug Administration, Ophthalmic Devices Panel (March 1982-July 1995)  
Coordinator for Optometry; Western Interstate Commission for Higher Education, University of Wyoming (October 1970-October 1990)  
Chairman; Future of Optometry and Optometric Education Study Committee (September 1981-July 1982)  
Member; U.S. Department of Health and Human Services; Food and Drug Administration, Ophthalmic Devices Section (August 1977-March 1982)  
Member; Project Advisory Committee, WICHE Project "Plans for the Development of a Regional Program of Optometric Education in the Western United States" (October 1977-July 1980)

## AMERICAN OPTOMETRIC ASSOCIATION

### Contact Lens Section

Member; (1982-Present)  
Chairman; (June 1986-July 1987)  
Chairman-Elect; (June 1985-June 1986)  
Vice-Chairman; (June 1984-June 1985)  
Secretary; (June 1983-June 1984)  
Nominating Committee (1996-1997)  
Residency Committee (1996-1998)

### Board of Trustees

Member; AOA Board of Trustees (June 1979-June 1982)  
Member; Medicare Task Force (June 1981-October 1984)

### Division Activities

Chairman; AOA Education and Manpower Division, Executive Committee (June 1973-November 1974)  
Member; AOA Primary Care Division, Executive Committee (June 1977-June 1979)  
Member; AOA Professional Development Division, Executive Committee (June 1976-June 1977)  
Member; AOA Educational and Manpower Division, Executive Committee (June 1971-June 1972)

James A. Boucher

Council Activities

Consultant; Accreditation Council on Optometric Education (June 1996 – Present)  
Member; Council on Optometric Education, Professional Degree Program Committee  
(July 1996-1998) Chair (July 1996-June 1997)  
Member; Council on Optometric Education (April 1988-June 1996) Chair; (July 1989-June 1996)  
Member; Council on Optometric Research (September 1986-July 1988)

Commission Activities

Member; Commission on Ophthalmic Standards (November 1977-June 1979)  
(June 1986-June 1988)  
Consultant; Commission on Ophthalmic Standards (March 1985-June 1986)  
Chairman; Commission on Ophthalmic Standards (November 1977-June 1979)

Committee Activities

Member; Fall and Mid Year Planning Committee (December 1991-June 1993)  
Member; Primary Care Symposium Committee (October 1985-September 1986)  
Chairman; NOW Week 1982 (January 1982-September 1982)  
Chairman; FTC - Eye Glasses - State Legislative Committee (November 1980-June 1981)  
Chairman; Special Board Committee on Definition of a Contact Lens Prescription  
(November 1979-June 1980)  
Chairman; AOA Committee on American National Standards Institute (June 1976-June 1979)  
Chairman; AOA Committee on Research and Development (June 1972-June 1973)  
Chairman; AOA Committee on Research and Standards (June 1970-June 1972)

Project Team Activities

AOA Representative; FAA Airman Vision Working Group (August 2002-August 2004)  
Member; Paraoptometric Education Study Project Team (July 1992-July 1993)  
Member; Council on Clinical Optometric Care Study Project Team (January 1992-June 1992)  
Member; Council on Optometric Education Study Project Team (July 1987-June 1988)  
Chairman; Long Range Planning Project Team (August 1982-September 1984)  
Chairman; Contact Lens Section Project Team (November 1980-June 1981)  
Chairman; AOA Project Team on Standards Laboratory Development (July 1977-November 1977)  
Chairman; AOA Project Team on Advertising (September 1975-March 1976)  
Chairman; AOA Project Team on Manpower Research and Development (June 1973-June 1974)  
Member; AOA Project Team on Consumerism/Consumer Concerns (June 1977-June 1978)  
Member; AOA Project Team on Standards for Quality Evaluations (June 1976-1978)

Congress Activities

Member; AOA Congress, Sub-committee on Education (February 1987-June 1988)  
Chairman; 1977 AOA Nominating Committee

James A. Boucher

Other AOA Activities

AOA Representative:

ANSI Z80.2 Contact Lens Sub-Committee (1985-1988)  
ANSI Z80 Parent Committee (1970-1980)  
ANSI Z80.1 Ophthalmic Lens Sub-Committee (1970-1980)  
ANSI Z80.1 Working Group on Optical Performance (1972-1979)  
ANSI Z80.5 Frame Standards Sub-Committee (1973-1979)

AMERICAN ACADEMY OF OPTOMETRY

Nominating Committee (1994) (1997-2001) Chair (1998-2001)  
Member; Membership Committee (1998-2004)  
Member; Judicial Committee (December 1987-December 1996)

WYOMING OPTOMETRIC ASSOCIATION

President (November 1976-July 1978)  
President-Elect (November 1975-November 1976)  
Vice-President (November 1973-November 1974)  
Treasurer (November 1970-November 1973)  
Secretary-Treasurer (November 1967-November 1969) and (September 1977-July 1981)  
Keyman/Keywoman Chairman (June 1977-July 1981)  
State Chairman; WOA Research Committee (November 1970-July 1981)  
State Chairman; WOA Assistance to Graduates and Undergraduates  
Committee (November 1969-November 1976)  
State Chairman; American Optometric Foundation (January 1970-January 1976)  
State Chair; Awards, Recognition, Scholarships (August 1982-Present)

COMMUNITY AND STATE ACTIVITIES

Member; State of Wyoming, Department of Health Medicaid Advisory Committee (1996 -2002)  
Member; College of Health Sciences, University of Wyoming Strategic Planning Committee  
(1994-Present)  
Member; State of Wyoming, Department of Health and Social Services,  
Division of Health and Medical Services Advisory Council (March 1988-March 1991)  
Chairman; (March 1989 - March 1991)  
Member; State Wide Health Coordinating Council (July 1982-January 1988)  
Chairman; (July 1986-January 1988)  
Vice-Chairman; (January 1985-June 1986)  
Chairman; Data Authority Committee (May 1985-September 1986)  
Member; Advisory Panel, University of Wyoming, School of Nursing (January 1983-June 1991)  
Member; Wyoming State Legislature, House of Representatives (January 1975-January 1977)  
Member; Health, Education and Welfare Committee (January 1975-January 1977)  
Member; Western Interstate Commission Higher Education Study Committee  
(June 1976-January 1977)  
Southeastern Wyoming Mental Health Board (August 1975-June 1981)

James A. Boucher

Wyoming Hospital Association, Trustees Council (October 1978-October 1980)  
Wyoming Hospital Association;Member (June 1969-November 1974),(November 1977-October 1984)  
Board of Directors (January 1979-October 1979)  
Wyoming Health Training Network - Laramie Branch (September 1975-November 1976)  
Chairman; Finance Committee (May 1976-November 1976)

Local

Albany County Hospital District - Board of Trustees Member (June 1969-November 1974),  
(November 1977-October 1984)  
President (September 1980-September 1983)  
Vice-President (June 1978-September 1980)  
Treasurer (1971-1974)  
Joint Conference Committee (June 1971-November 1974), (June 1978-October 1984)  
Albany County Mental Health Board Member (August 1972-November 1974),  
(August 1975-June 1979)  
Vice-President (June 1974-November 1974)  
Laramie Lions Club - Member (August 1966-Present)  
Chairman; Sight Conservation Committee (July 1977-July 1984)  
Laramie Chamber of Commerce (1966-Present)  
Envoys (Laramie Goodwill Ambassadors) (1975-1988)  
Rotary International (February 1973-June 1976)  
United Fund Board of Directors, Laramie, Wyoming, (February 1969-March 1971), (February 1974-March 1975)  
Laramie Jaycees (October 1966-June 1973)  
Vice-President (1968-1969)  
State Chairman (1970)  
Episcopal Church - Board Member, Department of College Work for  
State (February 1969-March 1971)

PUBLICATIONS – LECTURES

Boucher, J.A.; Poteet, G.M.; "Continuous Wear Contact Lenses" Contact Lens Spectrum Vol.19 (No 5, 2004)  
Boucher, J.A.; Poteet, G.M.; "GP Lens Decisions" Optometric Management, October 2003  
Boucher, J.A.; Bauscher, W.A.; "A Hard Look at Soft Bifocal Contact Lenses Fitting" Lecture, Shadow Ridge Symposium, February 26, 2001 Park City, UT.  
Boucher, J.A.; Bauscher, W. A.; "A Hard Look at Soft Bifocal Contact Lenses Fitting" Lecture – Paper, Sixth International Meeting, American Academy of Optometry, April 7, 2000, Madrid Spain  
Boucher, J.A.; "Long-Term Use of Saturn II and SoftPerm Contact Lenses for Keratoplasty and Keratoconus: A Case Report." International Contact Lens Clinics, Vol. 19, (No. 1 & 2, 1992)

James A. Boucher

Boucher, J.A.; "Fitting Characteristics of the SoftPerm Contact Lens." Lecture, SnowmassSkiConference, February 1, 1991, Steamboat Springs, Colorado

Boucher, J.A.; "Contact Lens Update." Lecture, Washington State Optometric Association, University of Washington, March 17, 1990, Seattle Washington.

Boucher, J.A.; "Vision, Comfort and Corneal Response Comparisons of SoftPerm and Saturn II." Paper, American Academy of Optometry, December 10, 1989. New Orleans, Louisiana.

Boucher, J.A.; "The New Saturn Lens." Sixth Annual Contact Lens Symposium, AOA Contact Lens Section, September 18, 1988, Boston Massachusetts.

Boucher, J.A.; "Contact Lens Update." Lecture, Eye Ski Seminar, February 26, 1988, Park City, Utah.

Boucher, J.A.; "New Advances in Combination Rigid/Soft Contact Lenses." Lecture, Contact Lens Association of Ophthalmologists Annual Meeting, January 19, 1988 Las Vegas, Nevada.

Boucher, J.A.; "Criteria for Predicting Successful Prescribing the Saturn II Contact Lens." Scientific Poster, Contact Lens Association of Ophthalmologists, January 1987, Las Vegas, Nevada.

Boucher, J.A.; "Criteria for Predicting Successful Prescribing the Saturn II Contact Lens." Poster Paper, American Academy of Optometry, December 13, 1986, Toronto, Canada.

Boucher, J.A.; "Prescribing Contact Lenses for the Astigmatic Patient." Lecture, 19th Annual North Central States Optometric Conference, 1985 Minneapolis, Minnesota.

Boucher, J.A.; "Prescribing the Saturn II Contact Lens." Lecture, 19th Annual North Central States Optometric Conference, 1985 Minneapolis, Minnesota.

Boucher, J.A.; "Saturn II - A New Lens on the Horizon." Lecture, 1984 Northern Rockies Optometric Conference, Jackson, Wyoming.

Boucher, J.A.; "Investigational Clinical Study of a Contact Lens Consisting of a Gas Permeable Center with a Soft Hydrophilic Skirt." Paper, American Academy of Optometry, December 10, 1983, Houston, Texas.

Worthen, D.M.; Boucher, J.A.; Buxton, J.N.; Lowther, G.; Talbott, M.; "Update Report on Intraocular Lenses." Ophthalmology, Vol. 88, (No. 5, 1981)

Boucher, J.A.; "Optometric Education - A Status Report." Journal of the American Optometric Association - Vol. 51, (No. 4, 1980)

Worthen, D.M.; Boucher, J.A.; Buxton, J.N.; Hayreh, S.S.; Lowther, G.; Reinecke, R.D.; Spencer, W.H.; Talbott, J.; Weeks, D.F.; "Interim FDA Report on Intraocular Lenses." Ophthalmology, Vol. 87, (No. 4, 1980)

Boucher, J.A.; Hunter, E.A.; King, V.M.; "The 1979 Revision of Z80.1 - The American National Standard Recommendations for Prescription Ophthalmic Lenses - The AOA Position." Journal of the American Optometric Association - Vol. 50 (No. 5, 1979)

James A. Boucher

Boucher, J.A.; "The Commission on Ophthalmic Standards - The American Optometric Association's Standards Development Program." Journal of the American Optometric Association - Vol. 50, (No. 5, 197

Boucher, J.A.; "The Use of Ophthalmic Standards in Practice; Present and Future Needs." Paper given at: Symposium on Applied Problems in Vision, National Academy of Sciences, Washington, D.C., April 9-10, 1979.

Boucher, J.A.; "ANSI Standards and Optometry." Lecture, American Academy of Optometry, December 9, 1977, Birmingham, Alabama.

Boucher, J.A.; "The Metric System - A Must." Journal of the American Optometric Association, Vol. 43, (No. 11, 1972)

Boucher, J.A.; "Research Going on in Optometry." Lecture, 74<sup>th</sup> Annual Congress American Optometric Association, 1971, Houston, Texas.

Boucher, J.A.; "Optometry and the Metric System." Paper given to a U.S. Congressional Committee, National Bureau of Standards, Washington, D.C., (1970)

Boucher, J.A.; "Common Visual Direction Horopters in Exotropes with Anomalous Correspondence." American Journal of Optometry and Archives of American Academy of Optometry, Vol. 44, (No. 10, 1967).

#### MASTERS DEGREE THESIS

Common Visual Direction Horopters in Exotropes with Anomalous Correspondence, M.S. Thesis, Indiana University, 1966.

Revised 05/05

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	:	Legerton et al.	)	Group Art Unit 2873
Appl. No.	:	10/657,061	)	
Filed	:	September 5, 2003	)	
For	:	HYBRID CONTACT LENS SYSTEM AND METHOD	)	
Examiner	:	Jessica T. Stultz	)	

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**DECLARATION OF WILLIAM E. MEYERS PURSUANT TO 37 C.F.R. § 1.132**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, William E. Meyers, declare and state as follows:

1. I am a United States citizen and I reside at 12427 North 129<sup>th</sup> Place, Scottsdale, AZ 85259.
2. I am currently Vice President of Science and Technology at Paragon Vision Sciences, 947 E. Impala Avenue, Mesa, AZ 85204. I have held this position for 9 years. My duties include research and development of new materials for contact lenses and regulatory affairs and quality control. Prior to this, I worked as a consultant to Rasor Associates, Inc. and Specialty Ultravision for about seven months, where my duties included consulting regarding the development of a contact lens design. While consulting with Rasor Associates, I worked on the development of a contact lens involving a combination of polymers. This lens was sold commercially under the name Epicon, but it was not a hybrid lens. Prior to this consulting position, I was Vice President of Research and Development at Pilkington Barnes Hind for 7 years, where my duties included research and development for contact lens materials and lens care products. Prior to this, I was Vice President of Research and Development at Syntex Ophthalmics for 5 years,

**Appl. No.** : **10/657,061**  
**Filed** : **September 5, 2003**

where my duties included development of new materials and manufacturing processes for contact lenses. Prior to this, I was a Division Head for the Biotechnology Division at the Southern Research Institute for 6 years, where my duties included research with respect to polymers. I have worked in the contact lens industry for the past 21 years.

3. I have a Doctorate in Biochemistry from Ohio State University, which I obtained in 1978. My thesis was regarding the use of synthetic polymers to mimic the activity of biopolymers. I also hold a Bachelor of Science in Biochemistry from Ohio State University, which I obtained in 1973.

4. I was a member and served as an editor of the national publication published by the Controlled Release Society. This organization dealt with the release of pharmaceuticals through polymers. I am a member of the Contact Lens Association of Ophthalmology (CLAO), which publishes a journal ("The Eye and Contact Lenses"). I read this journal regularly. I was on the guiding board for a Material Sciences Symposium held regularly in New Orleans, Louisiana. I attend this symposium regularly and have been a past presenter. I also participate in meetings of the International Society for Contact Lens Research (ISCLR).

5. I am a named inventor on several patents and patent applications, several of which are in the contact lens field. In addition, I have authored numerous publications and technical reports and made numerous technical presentations, many of which involve contact lenses and/or contact lens material science.

6. I currently serve as a consultant with SynergEyes, Inc., previously Quarter Lambda Technologies, Inc., the owner of the pending patent application. I am assisting SynergEyes, Inc. on the development of a hybrid contact lens. I do not hold stock or any ownership interest in SynergEyes, Inc.

7. I have worked in the contact lens industry for the past 21 years, including the research and development of polymers used in the manufacture of contact lenses. Further, I've been involved in research related to materials for rigid and soft contact lenses and their compatibility with the human eye. I have also worked with hybrid contact lenses. While at Barnes Hind around 1988-89, I became involved with hybrid contact lenses, including performing research and development. The hybrid contact lens, called the Saturn lens, had a soft hydrophilic peripheral skirt, and we experienced bonding problems, including the delamination of the contact lens at the

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junction. The commercially available Saturn hybrid contact lens had a low DK center and low DK skirt. I understand that the major problem with the Saturn lens is that it delaminated at the junction. The Softperm contact lens, which incorporated a change in the geometric shape of the Saturn lens, and which is currently commercially available, also has a low DK center and a low DK peripheral skirt. It is my understanding that the Softperm lens continues to have tearing problems.

8. I have reviewed the pending claims in the above-identified application. I have also reviewed GB Patent No. 1,417,650 ("Sohnges") and U.S. Patent No. 5,986,001 ("Ingenito"), the two references I understand the Examiner has used to reject the pending claims as being obvious. I disagree that the pending claims are obvious in view of Sohnges and Ingenito.

9. In my opinion, the combination of Sohnges and Ingenito would not render the pending claims obvious to one of ordinary skill in the art for at least the following reasons:

10. Sohnges does not disclose a hybrid contact having a hard central portion with a DK of at least  $30 \times 10^{-11}$ . In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens. Further, Sohnges discloses microlenses, which are smaller than a human cornea. If the lens of Sohnges was larger so as to serve the purpose of a hybrid contact lens, the lens would be too large to permit tear pumping or movement under the lens and would starve the cornea of oxygen. Moreover, Sohnges teaches away from using a hydrophilic skirt, and the materials identified in Sohnges are not hydrophilic. Indeed, there is no disclosure or suggestion in Sohnges to 1) provide a high DK central portion, 2) provide a hydrophilic skirt, or 3) bonding a high DK central portion to a hydrophilic skirt in any manner.

11. With respect to Ingenito, the lens disclosed uses an interpenetrating network of preformed uncrosslinked polymers. This combination results in a flexible material which is incompatible with the function of the rigid center in a hybrid contact lens. In addition, the uncrosslinked polymers disclosed in Ingenito could not be used as the soft peripheral skirt in a hybrid contact lens. The Ingenito lens is formed through softening and compressing the polymer mixture. There is no bonding occurring. Further, there is no suggestion to bond the material of Ingenito with any other material, let alone that disclosed in Sohnges. Therefore, one of skill in the art looking at these two references would not be able to combine the non-reactive uncrosslinked polymers of Ingenito with the material in Sohnges.

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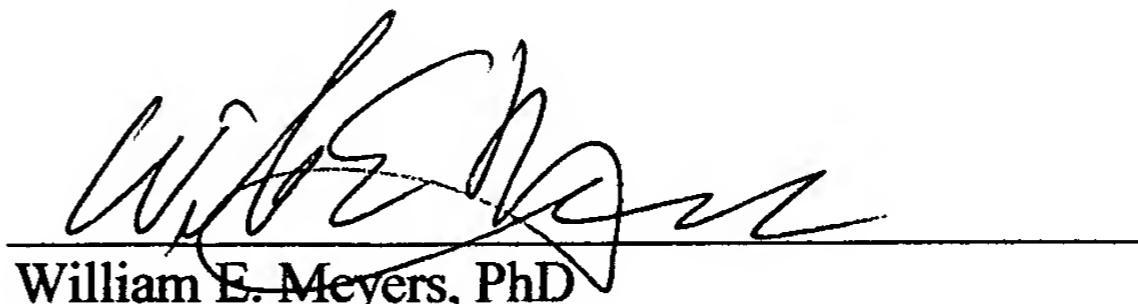
12. In order to provide a comfortable lens, it is important that the lens be wide enough to cover at least the cornea, which prevents the lens from excessive movement and eyelid interaction. With respect to hard contact lenses, although they provide superior vision, movement of the lens occurred often, causing discomfort with every blink. Further, foreign objects are free to migrate under the hard lens with tear exchange, causing pain and corneal trauma. With soft lenses, it is possible to manufacture a wider lens, which experiences less movement in the eye and less movement caused by eyelid interaction, resulting in less discomfort, and foreign bodies are prevented from migrating under the lens. However, soft lenses do not provide the visual quality of the rigid optics of a hard lens.

13. Therefore, there has been a long-felt need in the industry for a hybrid contact lens having a hard central portion with a high DK providing high quality vision and high oxygen permeability and a soft peripheral skirt providing greater comfort, as described above. I am aware since at least as early as 1988 of attempts that have been made to manufacture an improved hybrid contact lens. To the best of my knowledge, none of these efforts ever succeeded resulting in a commercial product.

14. In view of the long-standing efforts by others, and my knowledge of the contact lens industry over the past 21 years, I do not believe the claimed invention recited in the pending claims of the above-identified application are obvious in view of Sohnges and Ingenito.

15. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Dated: June 3 2005



William E. Meyers, PhD